

## 深圳坪山医疗器械仓储配送，医疗器械第三方物流资质

产品名称	深圳坪山医疗器械仓储配送，医疗器械第三方物流资质
公司名称	深圳市易达恒通供应链管理有限公司
价格	.00/个
规格参数	
公司地址	深圳市福田区南园街道上步南路1001号、1005号 锦峰大厦 医疗仓宝安石岩 前海保税仓 坪山综合保税仓
联系电话	13622393625 13622393625

## 产品详情

进口医疗器械注册证办理所需资料

境外医疗器械注册申请表

Application form for registration of import medical device

医疗器械生产企业资格证明

Legal Qualification certification for medical device manufacturing enterprise.

申报者的营业执照副本和生产企业授予的代理注册的委托书

A Copy of applicant 's business license and proxy for registration entrusted by the

Manufacturing enterprise

境外政府医疗器械主管部门批准或认可的该产品作为医疗器械进入该国（地区）市场的证明文件

Documents proving that the product can enter a certain country (or region) as medical

Device approved or accepted by the medical device competent departments of overseas governments

适用的产品标准（及说明）

Applicable product standard and instructions

医疗器械说明书

Specification for medical device

医疗器械检测机构出具的产品注册检测报告（适用于第二类、第三类医疗器械）

Test report on product registration given by medical device inspection institutions (applicable to Class II and Class III medical device)

医疗器械临床试验资料

Medical device clinical trials report.

生产企业出具的产品质量合格书

Product Quality Guarantee issued by the manufacturer certifying that the quality of the product to be registered for sale in China is exactly the same as that of the product marketed in the country (region) of origin.

生产企业在中国指定代理人的委托书、代理人的承诺书及营业执照或者机构登记证明

Proxy of assigned agent of the manufacturer enterprise in china, written Commitment of the agent and business license or registration certificate of the agent

在中国指定售后服务机构的委托书、被委托机构的承诺书及资格证明文件

Letter of Authorization for designated after-sales service agency in China and Letter of Promisa and business license of the authorized agency.

\*\*\*\* (有效期四年，有效期满前6个月应申请重新注册)